

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

February 10, 2010

8:00 a.m.	Call to Order Introduction of Committee	S. Gail Eckhardt, M.D. Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC

On the morning of February 10, 2010, the committee will discuss NDA 022-481, with the proposed trade name PIXUVRI (pixantrone dimaleate) injection, manufactured by Cell Therapeutics, Inc. The proposed indication (use) for this product is as a single agent treatment for patients with recurring or refractory (difficult to treat), aggressive Non-Hodgkin's Lymphoma (NHL) who have received 2 or more prior lines of therapy.

8:10 a.m.	Opening Remarks	
8:15 a.m.	<u>FDA Presentation</u>	
8:30 a.m.	<u>Sponsor Presentation</u>	<u>Cell Therapeutics, Inc.</u>
9:10 a.m.	<u>FDA Presentation</u>	<u>NDA 022-481</u>
9:50 a.m.	<i>Break</i>	
10:00 a.m.	Questions to the Presenters	
10:30 a.m.	Open Public Hearing	
11:00 a.m.	Questions to the ODAC and ODAC Discussion	
12:00 p.m.	<i>Lunch</i>	

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February 10, 2010

1:00 p.m.	Call to Order Introduction of Committee	S. Gail Eckhardt Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC

On the afternoon of February 10, 2010, the committee will discuss New Drug Application (NDA) 022-374, with the proposed trade name OMAPRO (omacetaxine mepesuccinate) for injection, manufactured by ChemGenex Pharmaceuticals. The proposed indication (use) for this product is for the treatment of adults with chronic myeloid leukemia (CML) bearing a genetic alteration known as the Bcr-Abl T315I mutation, and who have failed prior therapy with the drug imatinib.

1:10 p.m.	Opening Remarks
1:15 p.m.	<u>FDA presentation</u>
1:30 p.m.	<u>Sponsor Presentation</u> <u>ChemGenex Pharmaceuticals</u>
2:10 p.m.	<u>FDA Presentation</u> NDA 022-374
2:50 p.m.	<i>Break</i>
3:00 p.m.	Questions to the Presenters
3:30 p.m.	Open Public Hearing
4:00 p.m.	Questions to the ODAC and ODAC Discussion
5:00 p.m.	Adjourn